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Dated 17 March 2003

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P01/7700 0.00-0204887.4

Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

The Patent Office
Cardiff Road
Newport
South Wales
NP9 1RH

1. Your reference — SW/P16382

2. Patent application number *(The Patent Office will fill in this part)* — **0204887.4**

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

BEAUMONT, Terry
Far Mount Farm
Cumberworth
HD8 8YE
GB

Patents ADP number *(if you know it)*

If the applicant is a corporate body, give the country/state of its incorporation — 8335929001

4. Title of the invention — Beathing Equipment

5. Name of your agent *(if you have one)* — Harrison Goddard Foote

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

Belgrave Hall
Belgrave Street
Leeds
LS2 8DD

Patents ADP number *(if you know it)* — ~~14571001~~ 7631310002

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.
See note (d))

Patents Form 1/77

9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form	
Description	7
Claim(s)	
Abstract	
Drawing(s)	3

10. If you are also filing any of the following, state how many against each item.

Priority documents	
Translations of priority documents	
Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	
Request for preliminary examination and search *(Patents Form 9/77)*	
Request for substantive examination *(Patents Form 10/77)*	
Any other documents *(please specify)*	

11. I/We request the grant of a patent on the basis of this application.

Signature: Harrison Goddard Foote — Date: 1 March 2002

12. Name and daytime telephone number of person to contact in the United Kingdom: Siobhan Ward — 0113 233 0100

Warning

After an application for a patent has been filed, the Comptroller of the Patent Office will consider whether publication or communication of the invention should be prohibited or restricted under Section 22 of the Patents Act 1977. You will be informed if it is necessary to prohibit or restrict your invention in this way. Furthermore, if you live in the United Kingdom, Section 23 of the Patents Act 1977 stops you from applying for a patent abroad without first getting written permission from the Patent Office unless an application has been filed at least 6 weeks beforehand in the United Kingdom for a patent for the same invention and either no direction prohibiting publication or communication has been given, or any such direction has been revoked.

Notes

a) If you need help to fill in this form or you have any questions, please contact the Patent Office on 0645 500505.

b) Write your answers in capital letters using black ink or you may type them.

c) If there is not enough space for all the relevant details on any part of this form, please continue on a separate sheet of paper and write "see continuation sheet" in the relevant part(s). Any continuation sheet should be attached to this form.

d) If you have answered 'Yes' Patents Form 7/77 will need to be filed.

e) Once you have filled in the form you must remember to sign and date it.

f) For details of the fee and ways to pay please contact the Patent Office.

SENSING DEVICE

The present invention relates to a sensing device suitable for non-invasive monitoring of physiological factors, the device being particularly suitable for location within the ear canal. The invention also relates to duplex communication systems for use with a sensing device.

Systems for the monitoring of critical physiological factors are known. US 07/272,146 discloses the use of a nasal septum probe or oxisensor, which is used with a conventional medical pulse oximeter. The application discloses the modified use of a nasal septum probe, or oxisensor, used with a conventional medical pulse oximeter. The nasal septum probe fits over a patient's nose bridge, or septum. The nasal septum oxisensor is modified to mount within the nose bridge covering portion of a conventional aircrew member face mask so that the blood oxygen saturation and pulse rate of the aircrew member can be monitored without any noticeable interference with, or extra effort by, the aircrew member.

A pulse oximeter calculates blood oxygen saturation from the different rates at which oxygenated haemoglobin and reduced haemoglobin absorb light of different wavelengths or frequencies. Typically, two wavelengths of light are used, one in the red portion of the spectrum and the other in the infra-red. Also typically, absorption of the infra-red wavelengths is much less sensitive to blood oxygen saturation levels than is absorption of the red wavelengths. The intensity of a particular infra-red wavelength remaining after passing through vascular tissue can serve as a constant against which to measure the intensity of a particular red wavelength remaining after passing through the same vascular tissue. Pulse rate is calculated from the timing of the relative rise and fall of the amount of light absorbed at each wavelength.

The pulse oximeter probe prior art has placed light emitting diodes (LEDs), and corresponding light sensors, over a variety of body appendages having sufficient vascular tissue. Such appendages include a finger, an ear pina, or ear lobe, the nasal

septum as previously mentioned, and the scalp. The prior art frequently refers to ear oximeters, but in most cases it refers to oximeters using probes, or oxisensors, that mount across the ear lobe.

US 5,213,099 describes a sensing device comprising physiological sensing means in the form of a probe for measuring blood oxygen saturation level and a pulse monitor. The device comprises means to locate the sensing means inside an ear canal. The device is specifically designed as a non-invasive, unobtrusive physiological monitor for a pilot or aircrew member of high performance aircraft. Placement of the probe inside the relatively dark ear canal is greatly advantageous as it reduces sensitivity to error from external light sources and allows measurement of blood oxygen saturation at a location as near as possible to the blood supply to the brain of an air-crew member. This is due to the fact that the main artery that supplies the brain also supplies the timpanic membrane. The device is incorporated as part of a protective ear plug already issued to aircrew members.

Since the device of US 5,213,099 effectively seals off the auditory meatus into which it is plugged, the user of the device suffers from various problems. These include an uncomfortable feeling of pressure in the ear canal, sweat in the ear, pollution by cerumen and loss of sound localization when the auditory meatus is blocked off.

According to a first aspect of the present invention there is provided a sensing device comprising;

a) physiological sensing means; and

b) locating means to locate the sensing means inside an ear canal

characterised in that the locating means is provided with an aperture which, when the sensing device is fitted in the ear canal, allows motion of air in and out of the ear canal.

Placement of the device of the present invention inside the ear canal or auditory meatus has the important advantages of reduced sensitivity to error from external

light sources and measurement of important parameters such as blood oxygen saturation and core temperature as near as possible to the blood supply to the brain of the wearer. Due to the presence of the aperture the ear canal is open to ambient air and the above identified problems which would otherwise result due to location of a device within the ear canal of the user are greatly reduced.

Preferably the locating means is substantially U-shaped and the aperture is defined by the trough between each arm of the U.

Preferably the locating means is made of pliable material and can be adapted to fit comfortably within the ear canal.

Preferably the locating means is made of material which is a good heat conductor.

Most preferably the locating means is made of silicone or any other like material.

Preferably the physiological sensing means comprises an infra-red receiver and transmitter.

Preferably the physiological sensing means comprises a temperature sensor and a heat-transfer tip.

Preferably said locating means is provided with adjusting means such that one device can be comfortably accommodated by a multiplicity of users, i.e.'one size fits all'.

In one embodiment of the invention the adjusting means is provided as a protrusion which projects from the surface of the securing means and which in use ensures secure engagement of the device within the ear canal.

Preferably the sensing device is provided with securing means to secure the device on the ear of the user.

Preferably the securing means comprises an ear clip which surrounds the ear.

The securing means may be designed to go around the top or bottom of the ear.

Applications of a device of the present invention include use within the emergency, medical and military services. The device also has applications within the industrial sector for the monitoring of workers in hazardous areas.

It will be appreciated that communications between the user of the device and the person monitoring the physiological parameters will be desirable. This would be particularly important for example in patient monitoring.

Communication earpieces are known. US 5,659,620 (Kuhlman) describes an ear microphone which is adapted to be disposed and retained in the outer ear region, i.e., outside the auditory meatus. The device is suitable for use with portable telephones or radios.

The disclosure of US5,659,62 teaches away from the use a device which is designed for arrangement within the auditory meatus.

Embodiments of the invention also seek to provide a physiological monitor which provides a communications unit.

Accordingly the sensing device of the present invention may further comprise communication means comprising a speaker and a microphone.

Preferably a feeder cable connects the sound generator and microphone unit to an external recording and monitoring unit. The feeder cable can be replaced by the use of wireless transmission.

Preferably the speaker is located within the aperture of the U-shaped locating means.

Preferably the microphone contacts the front part of the outer ear. Preferably the microphone is a bone microphone and collects vibrations transmitted by the jawbone which passes near the front part of the outer ear. These vibrations are generated in the throat and vocal cords of the user upon talking.

Preferably the microphone is enclosed by a bubble of air. When the device is in use, the air bubble makes contact with the ear-bone against which it is placed and transmits vibrations in the air within the bubble to a microphone and down a feeder cable to an external recording and monitoring unit.

Preferably the communication means and the locating means are formed as separate components, each component suitably adapted for reversible attachment with said other component. Reversible attachment facilitates general maintenance and cleaning of the sensing device. In an alternative embodiment the communication means is integral with the locating means.

Due to the nature of potential applications of the present device mentioned above, it will be apparent to one of skill in the art that full duplex communication, as opposed to merely simplex communication, is clearly desirable. It is known that for an ear microphone to be used for full duplex, sufficient separation between input and output must be present in order to avoid self-resonance. Although US5,659,620 makes reference to the advantage of full duplex communication the document does not enable such levels of communication.

According to a second aspect of the present invention there is provided communication means comprising;

a) a speaker

b) a microphone

characterised in that the speaker is associated with vibration absorbant material.

Preferably both the speaker and the microphone are associated with vibration absorbant material.

Preferably the speaker and/or the microphone is associated with two layers of absorbant material.

Preferably the first vibration absorbing material is a soft silicone sealant.

Preferably the second vibration absorbing material is thermoplastic elastomer or thermoset silicone.

Preferably the second vibration absorbing material has a sure hardness of 30 to 60 %

The absorbant material serves to absorb vibrations emitted by the speaker and thus prevent transmittal of these vibrations to the microphone. Accordingly the communication means of the present invention allows for full duplex communication.

The present invention is illustrated by the accompanying drawings wherein;

Figure 1 shows the working assembly comprising locating means (1) and communication means (2) complete with securing means ie ear surround (3) and cable (4).

Figure 2 shows detail of the physiological sensing means (5) and adjusting means (6) located on the locating means (1).

Figure 3 shows the bubble (7) surrounding the microphone (8) of the communication means (2).

Figure 4 shows the aperture or groove (10) provided by the U shaped locating means (1) and the location of the speaker (11) therewithin.

Figures 5 to 8 show further detail of the sensing device.

Figure 9 shows the sensing device located in the inner ear of a user.

Figure 1

Figure 2

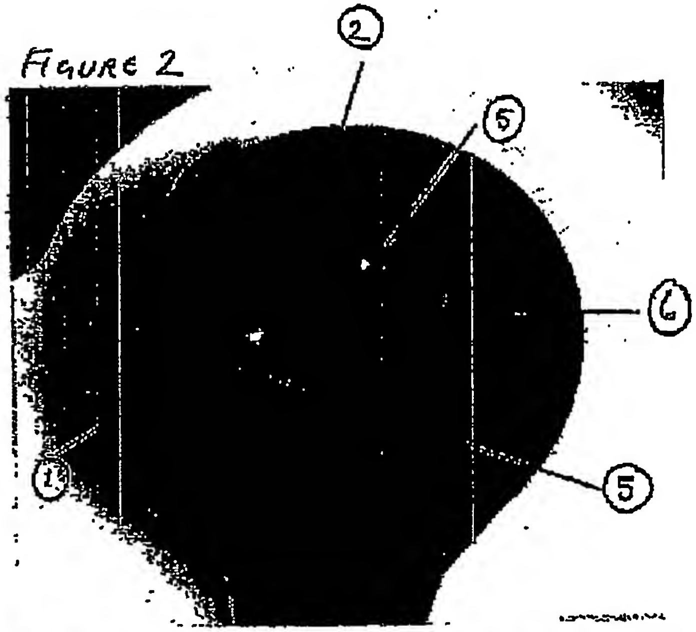


Figure 3

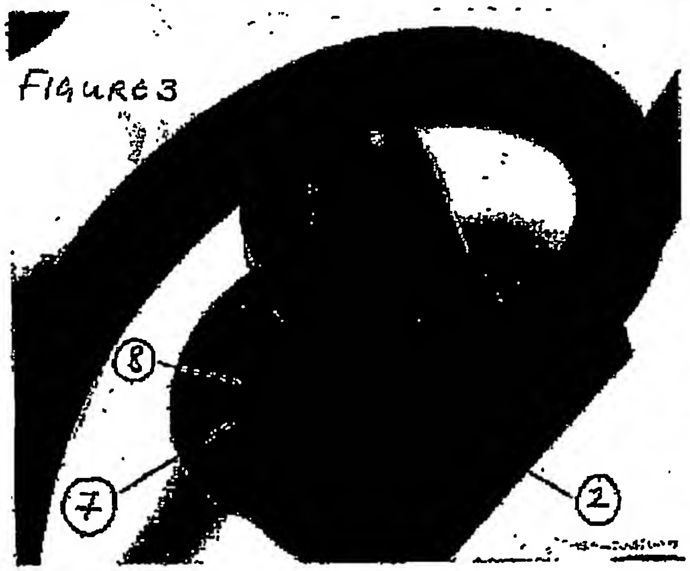
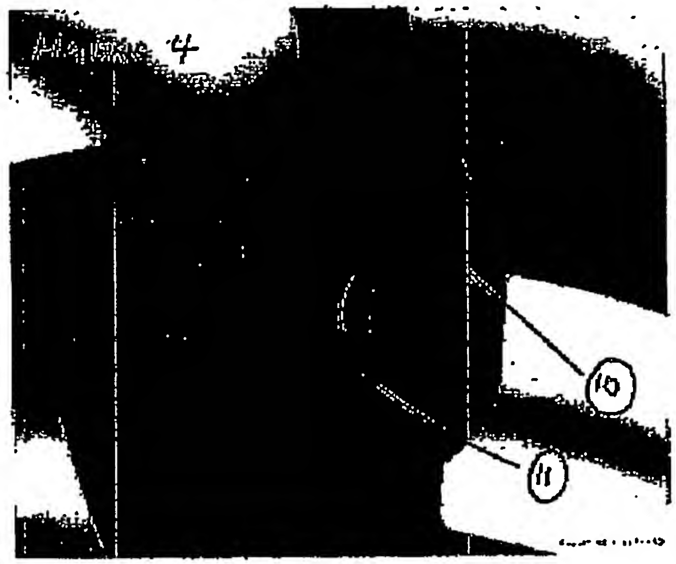


Figure 4



1 BEH Inner Ear Sensor

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FIGURE 5

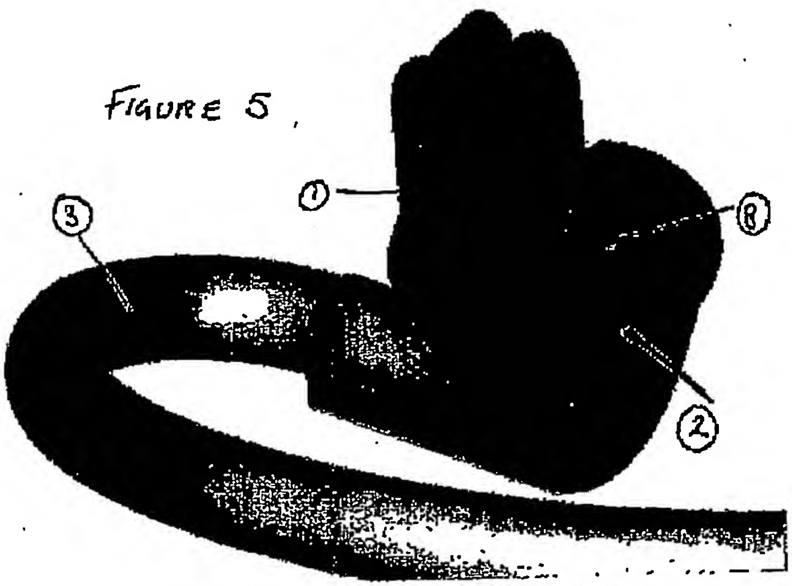


FIGURE 6

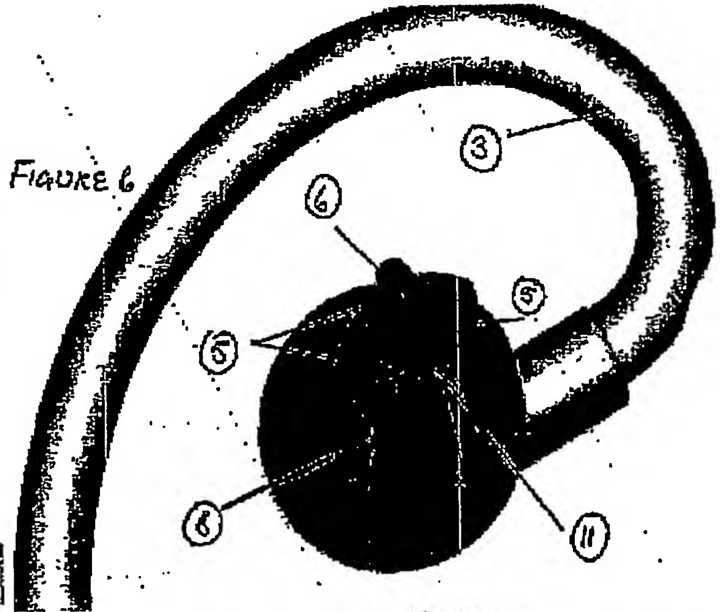


FIGURE 7

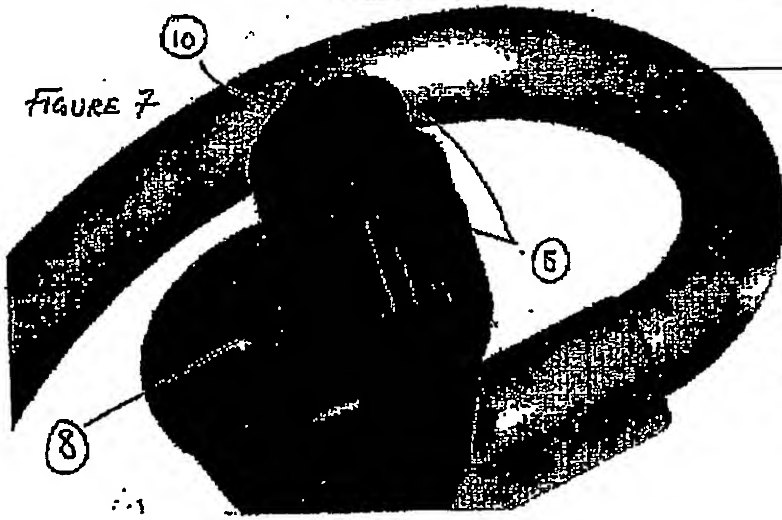
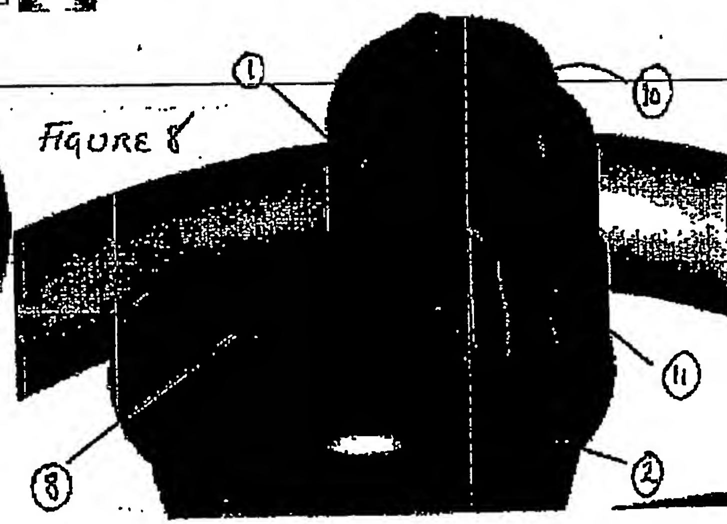


FIGURE 8



(2) BEH Inner Ear Sensor

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FIGURE 9;